

REMARKS/ARGUMENTS

On December 24, 2003, Applicants filed a Response to the Final Office Action of September 26, 2003. On January 20, an Advisory Action was mailed to Applicants in which the Examiner argued that because Applicants have introduced newly submitted limitation "*valerian oil produced by an alkali treatment*" into the claims, which would require further consideration, as well as new grounds of rejection, the amendment as filed on December 24, 2003 has not been entered.

After further consideration, Applicants have decided to file an RCE for continuing prosecution of the case. A withdrawal of the Final Office and an entry of the Response as filed on December 24, 2003 are therefore respectfully requested. In addition, a new section, with a subtitle of "Response to Advisory Action", is added to the end of the December 24, 2003 response, traversing Examiner's allegations raised in the Advisory Action. A reconsideration of the above-identified application is respectfully requested.

Additionally, Applicants discovered that the 132 Declaration they submitted accompanying the response on December 24, 2003 was defective due to an inadvertent deletion of Paragraph 4, probably due to electronic transmission errors, even though Applicants had argued no anticipation and non-obviousness in reliance on the information provided in this paragraph (See p. 9 and p. 11-12, *infra*). To correct this inadvertent mistake, an unsigned 132 Declaration showing all of the contents of the document is attached to this submission. The signed document will be submitted in a later time.

REMARKS SUBMITTED ON DECEMBER 24, 2003

In the Final Office Action dated September 26, 2003, claims 4 and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claim 10 is rejected under 35 U.S.C. § 102(b) as being anticipated by Warren et al., EP 0 183 436. Claims 1, 4, 13, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shoji et al. JP 10-204473. Claims 1, 4, 5, 10, 11, 13 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tanida et al. JP 01-254628. Claims 1, 4, 5, 10, 11, 13 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren et al. EP 0 183 436. Claims 1, 4, 5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tanida et al., in view of Shoji et al. Claims 1, 4, 5, 10, 13, and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Warren et al., in view of Tanida et al., and Shoji et al. Claims 3, 6, 9, and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tanida et al.

In response to the objections and rejections, Applicants have cancelled claims 1-4, 7-9 and 13-14, and amended claim 10. Also, to counter the Examiner's assertion that Applicants have not provided any scientific data showing any unexpected and/or unusual results between the use of valerian oil (as disclosed by Warren et al.) and the use of fatty-acid-removed valerian oil (as claimed in the present claimed invention), and the difference between heat treated-valerian oil (as disclosed by Tanida et al.) and alkali treated-valerian oil (as claimed in the present claimed invention), a 132 Declaration signed by one of the inventors, Ken Shoji, is attached together with this response. Applicants respectfully submit that the amendments of claims 5 and 10 have overcome the rejections for the reasons set forth below.

Claim Objections

Claims 4 and 9 are objected as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In response to the objections, Applicants have cancelled claims 4 and 9 so that this issue is moot.

Claim Rejections – 35 U.S.C. § 112

Claim 13 is rejected under 35 U.S.C. § 112 as being indefinite.

In response to the rejections, claim 13 is cancelled so that the issue is moot.

Claim Rejections under 35 U.S.C. § 102(b)

Claim 10 is rejected under 35 U.S.C. § 102(b) as being anticipated by Warren et al.

Claims 1, 4, 13, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by Shoji et al. Claims 1, 4, 5, 10, 11, 13, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by Tanida et al.

In response to the rejections, Applicants have cancelled claims 1-4, 7-9, and 13-14. Thus, the only claims that are still of concern and still under the rejections are claims 5, 10, and 11.

Claim 5 is amended to further clarify that the fatty-acid-removed valerian oil is produced by an alkali treatment. This fact is recognized by the Examiner (e.g., by citing Shoji et al. on pages 4, and 5) and supported by the application on for example, Paragraphs [0018], [0021], and Example 1. Claim 10 is also amended to further clarify that the phrase "reduce cortisol

concentration in a human body" is NOT an intended use language by ensuring that the "reduce cortisol concentration" phrase in the preamble becomes a claim limitation.

"Anticipation under 35 U.S.C. § 102 requires that disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Electro med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994). *See also Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Applicants respectfully submit that because not each and every limitations of the independent claims of the present claimed invention, as amended, are found in the above identified prior art, Applicants' claimed invention is not anticipated by the cited prior art.

Claim 5 is Not Anticipated By Tanida et al., JP 10-204473

Tanida et al. teach a valerian oil distilled out at $\leq 80^{\circ}\text{C}$ under 0.08 mmHg vacuum that is free of malodor. As acknowledged by the Examiner, Tanida et al. do not teach that the valerian oil is free from fatty acid.

Claim 5, as amended, recites as follows:

"A method for relieving stresses in humans comprising inhaling an effective quantity of a fatty-acid-removed valerian oil produced by alkali treatment; wherein said fatty-acid-removed valerian oil is an active component of a perfume; and wherein said stress is relieved due to a reduction in cortisol concentration in said humans."

As evident by the scientific data provided in paragraph 4 and Table 1 of the enclosed 132 Declaration, the fraction of valerian oil that is used by Tanida et al. (i.e., a fraction distilled out at $\leq 80^{\circ}\text{C}$) is not free from fatty acids, because the boiling point of isovaleric acid (the majority

fatty acids in valerian oil) is 176°C so that at the temperature of $\leq 80^{\circ}\text{C}$, the majority of the fatty acids are not distilled out of the valerian oil. Alternatively, if heat treatment is high enough to be used to sufficiently remove all of the fatty acids, the valerian oil thus produced would be devoid of many other components due to the fact that these components have similar boiling points as that of the isovaleric acid. Since the fatty-acid-removed valerian oil is NOT the same as the fraction of valerian oil distilled out at $\leq 80^{\circ}\text{C}$, the amended claim 5 is not anticipated by Tanida et al.

Claim 10 is Not Anticipated by Either Warren et al. Or Tanida et al.

The amended claim 10, as amended, recites as follows:

"A method for decreasing cortisol value in humans comprising allowing said humans to inhale an effective quantity of a fatty-acid-removed valerian oil produced by an alkali treatment so as to decrease said cortisol value in said humans."

First, as acknowledged by the Examiner, Warren et al. do not teach or suggest the use of a fatty-acid-removed valerian oil produced by an alkali treatment. Also, as indicated in Figure 1 and Paragraph 3 of the enclosed 132 Declaration, the effect of a fatty-acid-removed valerian oil on stress relieve is definitely superior to that of valerian oil alone.

Secondly, unlike what is alleged by the Examiner that "decreasing cortisol value" is an intended use language, this term is embedded in both the preamble and the body of the amended claim 10. Language in a preamble is a limitation on a claim if "its appearance in the count gives 'life and meaning' to the manipulative steps." See Kropa v. Robie, 187 F.2d 150, 152 (CCPA 1951); See also Locite Corp. v. Ultraseal Ltd., 781 F.2d 861 (Fed. Cir. 1985); Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615 (Fed. Cir. 1995);

C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340 (Fed. Cir. 1998). In the amended claim 10, the phrase "decrease in cortisol value in humans" in the preamble is a necessary limitation because it constitutes the patentability of the claim since what is claimed is the "new use." Also, the phrase "decrease in cortisone value in humans" in the preamble clearly "breathes life and meaning" into the claim because without the "use," the claim becomes meaningless. Thus, the phrase "decrease in cortisol value in humans" in the preamble is a claim limitation as defined by the Federal Circuit. Therefore, the amended claim 10 is definitely not anticipated by Warren et al.

As to Tanida et al., Applicants incorporate by reference their arguments in support of no anticipation of Claim 5 over Tanida et al. (*supra*). Since Tanida et al. do not teach the "decrease in cortisol value" and also do not use "fatty-acid-removed valerian oil", the amended claim 10 is not anticipated by Tanida et al.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 1, 4, 5, 10, 11, 13 and 14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Warren et al. In addition, claims 1, 4, 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tanida et al., in view of Shoji et al. Furthermore, claims 1, 4, 5, 10, 13, and 14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Warren et al., in view of Tanida et al., and Shoji et al. Finally, claims 3, 6, 9 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Tanida et al.

As indicated previously, claims 1, 3, 4, 9, and 13-14 are cancelled. Claim 6 is a dependent claim of claim 5, and claim 11 is a dependent claim of claim 10, thus, if claims 5 and 10 are patentable over the prior art, claims 6 and 11 should also be patentable.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), the prior art reference must teach or suggest all the claim limitations. See MPEP § 706.02(j), citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants incorporate by reference their arguments submitted on July 17, 2003, in traversing the unobvious rejections under 35 U.S.C. § 103(a). Applicants further supplement their arguments as shown below:

Claim 5 is Not Obvious Over Warren et al., Tanida et al. Or Shoji et al., Alone or In Any Combination

In response to the multiple rejections under different combination of prior art, Applicants have amended claim 5 to clarify (a) that the fatty-acid-removed valerian oil is produced by an alkali treatment; and (2) that the reduction of cortisol value in human body is clearly a claim limitation by modifying the last "wherein" clause to recite -- wherein said stress is relieved due to a reduction in cortisol concentration in human body --.

In addition, in response to the Examiner's assertion that Applicants have not presented any scientific data in support of the differences in stress relieving effect between fatty-acid-removed valerian oil (i.e., claimed in the present invention), and valerian oil (i.e., disclosed in Warren et al.) or a fraction of the valerian oil distilled at $\leq 80^{\circ}\text{C}$ (i.e., Tanida et al.), Applicants have submitted a 132 Declaration to show that the fatty-acid-removed valerian oil has superior stress relieving capacity to valerian oil, and the fatty-acid-removed valerian oil produced by

alkali treatment contains different components than the fraction of valerian oil after being distilled to $\leq 80^{\circ}\text{C}$. Thus, it is clear that Warren et al. or Tanida et al. alone or in combination do not teach or suggest the invention claimed in the amended claim 5.

As to Shoji et al., as acknowledged by the Examiner, there is no teaching nor suggestion by Shoji et al. that the fatty-acid-removed valerian oil has stress relieving effect. Thus, it is clear that Shoji et al. alone do not teach nor suggest the invention claimed in the amended claim 5.

As to the combined teachings of Tanida et al. in view of Shoji et al., or Warren et al. in view of Tanida et al. and Shoji et al., the key limitation that "said stress is relieved due to a reduction in cortisol concentration in said humans" is clearly missing in all of the prior art references.

The Examiner's argument that the limitation of "reducing cortisol concentration in a human body" is an intended use language is without merit, particularly because in this case the amended claim 5 is a "method of use" claim, not a product claim, so that the "inherency" issue raised by the Examiner does not apply to the claim (because a new use of an old compound is clearly patentable under 35 U.S.C. §§ 100 & 101). Please note that even if the Examiner construes the "reducing cortisol concentration" limitation to be a functional limitation, it is known that functional language should be considered to be a limitation. See e.g., Pac-Tec, Inc. v. Amerace Corp., 903 F.2d 796, 801 (Fed. Cir. 1991).

Therefore, the amended claim 5 is not obvious over Warren et al., Tanida et al., or Shoji et al. alone, or over Tanida et al. in view of Shoji et al., or Warren in view of Tanida et al. and Shoji et al. Applicants respectfully request that the rejections be withdrawn.

Claim 10 is Not Obvious Over Warren et al., Tanida et al. Or Shoji et al., Alone or In Any Combination

In addition to the arguments shown above (*supra*), claim 10 is also not obvious over Warren et al., Tanida et al., or shoji et al., alone or in any combination for the following reasons.

Claim 10 is a "method of use" claim directed to a method of reducing cortisol value in humans. Under the current U.S. Patent Law, a new use of a known process, machine, manufacture, composition of matter, or material is a patentable invention under 35 U.S.C. §§ 100 & 101. See 35 U.S.C. § 100(b) ("The term 'process' means process, art or method, and includes a new use of a know process, machine, manufacture, composition of matter, or material"); 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title").

The preamble in a "method of use" claim is certainly a limitation to the claim because it "breathes life and meaning" into the claim and is a "necessary" element in determining the patentability of the invention. In addition, to ensure that the limitation of "reducing the cortisol concentration" is to be considered as a claim limitation, Applicants have amended claim 10 to include the phrase "to inhale an effective quantity of a fatty-acid-removed valerian oil produced by an alkali treatment so as to decrease said cortisol value in said humans" in the body of the claim. This further strengthens Applicants' position that the decrease in cortisol value in humans is a limitation to Applicants' "method of use" claim.

Thus, the amended claim 5 is not obvious over Warren et al., Tanida et al., or Shoji et al. alone, or over Tanida et al. in view of Shoji et al., or Warren in view of Tanida et al. and Shoji et al. Applicants respectfully request that the rejections be withdrawn.

Claims 6 and 11 are Not Obvious Over Warren et al., Tanida et al. Or Shoji et al., Alone or In Any Combination

It is well-settled that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. See, e.g., In re Fine, 837 F.2d 1071 (Fed. Cir. 1988). Since claim 6 is a dependent claim of claim 5, and claim 11 is a dependent claim of claim 10, since claims 5 and 10, as amended, are not obvious over Warren et al., Tanida et al., or Shoji et al., alone or in any combination, claims 6, and 11 are not obvious over Tanida et al.

RESPONSE TO ADVISORY ACTION

In the Advisory Action, the Examiner raised the following issues: First, Applicants' newly added limitation "valerian oil *produced by an alkali treatment*" is submitted after Final, therefore, it cannot be entered. (See Advisory Action at page 2, ¶1). Secondly, the 132 Declaration filed accompanying the Response is insufficient to overcome the rejections as set forth in the last Office Action because "the Declaration does not establish that the presence of fatty acids in valerian oil would have a detrimental effect upon the desirability of reducing stress." (emphasis in original) (See Advisory Action at page 2, ¶ 3).

With regard to the Examiner's first argument for refusal to enter Applicants' Response filed on December 24, 2003, the issue is now moot because filing of an RCE effectively removes the finality of the any Office action and "an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability" is permissible. See 37 CFR § 1.114(c). The limitation of "valerian oil *produced by an alkali treatment*" is fully supported by the Specification on for example, Paragraphs [0018], [0021], and Example 1. No new matter has been introduced.

With respect to the Examiner's second argument that Applicants failed to establish that the presence of fatty acids in valerian oil would have a detrimental effect upon the desirability of reducing stress, first, Applicants would like to point out that nowhere in the U.S. patent statute, a finding of "detrimental effect" as a factor for determining patentability is required.

Also, contrary to the Examiner's assertion, the 132 Declaration clearly has provided a side-by-side comparison between the claimed invention and that of Warren's. In particular, Paragraph 3 and Figure 1 of the Declaration clearly has shown a comparative study between the stress-relieving effect of the fatty-acid-removed valerian oil produced by an alkali treatment with the valerian oil (without fatty acid-removal). The results as shown in Figure 1 demonstrate that the fatty-acid-removed valerian oil is significantly better than the valerian oil without fatty acids removal in terms of stress-relieving effect. Please note that because Warren does not disclose a fatty-acid-removed valerian oil, Applicants' claimed invention is not anticipated or obvious over Warren since the prior art does not disclose all of the claimed elements.

Finally, as stated above, Paragraph 4 of the 132 Declaration was omitted when it was originally submitted. This paragraph provides an scientific finding and explanation with regard to the distinction between the fatty acids-removed valerian oil produced by Applicants (i.e., by an alkali treatment) and Tanida's valerian oil (i.e., a fraction taken from heat treatment of $\leq 80^{\circ}\text{C}$). Please note that because Applicants' valerian oil is alkali treated, which is distinctively different from Tanida's heat-treated valerian oil, Applicants' claimed invention is not anticipated or obvious over Tanida since the prior art does not disclose the alkali treated valerian oil.

In view of the foregoing, the rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

A handwritten signature in black ink that reads "Fei-Fei Chao". The signature is written in a cursive, flowing style.

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